



STATE OF MICHIGAN
DEPARTMENT OF COMMUNITY HEALTH
POLICY AND PROCEDURE MANUAL
POLICY AND PROCEDURE

CHAPTER

Public Health

NUMBER

11.3

EFFECTIVE DATE

November 19, 2010

SUBJECT

Guidelines for Review and Approval of Research Using Dried Blood Spots

Page 1 of 3

A. PURPOSE

The purpose is to establish the process for the Department of Community Health (DCH) to review research that proposes to use newborn screening dried blood spot specimens.

B. REVISION HISTORY

None

C. DEFINITIONS

DBS Review Coordinator means an individual designated by the Deputy Director of the Public Health Administration to provide logistical support for scientific merit review of research that proposes to use DBS.

Dried Blood Spot (DBS) means the blood specimen collected from the heel of a newborn for screening for hereditary disorders, as required by the Michigan Public Health Code, Act 368 of 1978, MCL 333.5431.

Director means the Director of the Department of Community Health, or designee.

Identifying information means information about an individual that is identifiable or potentially identifiable of an individual.

DCH IRB means DCH's Institutional Review Board established under DCH's Federal Wide Assurance to review all human subjects' research that is sponsored by, or involves DCH.

IRB approval means approval of research by DCH's IRB.

Michigan BioTrust for Health means the DCH initiative to make remaining DBS from newborn screening more available for medical and public health research by storing them in optimal conditions and promoting their availability to researchers.

DBS Program Representative means: State Registrar, Director of the Bureau of Laboratories and Director of Bureau of Epidemiology or designee.

BioTrust Scientific Advisory Board or BioTrust SAB means a board of scientists established consistent with the requirements of Ad. Rule 325.9055 and appointed by the Director for participation on scientific advisory panels that review proposed research covered by this policy for scientific merit.

BioTrust Scientific Review Panel or BioTrust SAP means a panel of at least three members selected from the Scientific Advisory Board to review a specific research proposal.

D. POLICY

It is the policy of the DCH to provide guidelines and monitor the implementation of the BioTrust Scientific Advisory Board review process for research that proposes to use DBS made available for potential research, whether identified or not.



STATE OF MICHIGAN
DEPARTMENT OF COMMUNITY HEALTH
POLICY AND PROCEDURE MANUAL
POLICY AND PROCEDURE

CHAPTER

Public Health

NUMBER

11.3

EFFECTIVE DATE

November 19, 2010


SUBJECT

Guidelines for Review and Approval of Research Using Dried Blood Spots

Page 2 of 3

E. PROCEDURE

Responsibility	Action
Director	Appoints members to DCH's BioTrust Scientific Advisory Board (upon recommendations from DCH staff, research institutions and other organizations) who are available for review of research proposing use of DBS. The term for each member shall be two years and may be renewable by the Director. To ensure availability of individuals with appropriate expertise, the Director may make short term appointments or appointments for specific research proposals.
DBS Review Coordinator	<ul style="list-style-type: none"> • Serves as primary point of contact to ensure completion of scientific review of research proposing use of DBS. • Must have approved IRB training. • Tracks status of reviews and outcomes. • Provides support services as directed by the DBS Program Representatives. <ul style="list-style-type: none"> ○ Enters information into shared log or tracking system to monitor status and outcome of reviews covered by this policy. ○ Assures that relevant DCH programs are notified when the research proposes to make use of other data that are governed by administrative regulations that require review by other scientific review boards. ○ Summarizes concerns and questions of panel members and communicates with researcher, distributing researcher's responses and any adjustments to the protocol to the panel until the needs and concerns of the panel are appropriately addressed. ○ Coordinates and consults with the Administrator of the IRB as indicated. ○ Following a recommendation to approve the proposal by the BioTrust Scientific Review Panel and DCH IRB, forwards the research proposal with a summary of panel recommendations for review by the DBS Program Representatives. • Notifies IRB Administrator, BioTrust Scientific Review Panel and research applicant of the review outcome.
DBS Program Representative	<ul style="list-style-type: none"> • On an annual basis or as needed, reviews appointments to the BioTrust Scientific Advisory Board specifically for appropriateness of members who can provide expert review of research proposing use of DBS. Make recommendations to the Director on adding or discontinuing appointments. • Provide oversight of the review process. <ul style="list-style-type: none"> ○ Select at least three members of the BioTrust Scientific Advisory Board to serve on a BioTrust Scientific Review Panel to review a specific research proposal. Communicates with panel members relative to the review.

	<p align="center">STATE OF MICHIGAN DEPARTMENT OF COMMUNITY HEALTH POLICY AND PROCEDURE MANUAL <i>POLICY AND PROCEDURE</i></p>	CHAPTER
		Public Health
		NUMBER
		11.3
		EFFECTIVE DATE
		November 19, 2010
SUBJECT		
Guidelines for Review and Approval of Research Using Dried Blood Spots		Page 3 of 3

	<ul style="list-style-type: none"> o If a research proposal includes a request for additional data or specific DBS based on stated criteria, the DBS Program Representatives will ensure the appropriate program responsible for the data has insight into the selection of the members of the BioTrust Scientific Review Panel or that their own respective advisory board has reviewed and approved the proposal if needed.
BioTrust SAB Scientific Review Panel	<ul style="list-style-type: none"> • Panel members review research proposals. Review criteria include assessing applicant qualifications/capabilities and scientific merit of the proposal. • Panel members can: (1) request research applicants provide additional information or clarification, (2) state specific concerns on the study proposal or methodology, and (3) comment on strengths, weaknesses or special concerns relative to the proposal. • Scientific Review Panel members make approval or disapproval recommendations. A recommendation for approval is required from a minimum of two panel members or by the simple majority if more than 3 members are appointed to a specific panel.

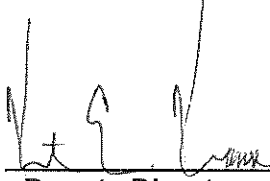
F. REFERENCES

Michigan Public Health Code, Act 368 of 1978, MCL 333.2611, 333.2619, 333.5431, 333.5717, 333.5721, 333.9207, 333.9227.
Michigan Administrative Code, R 325.167; R 325.9055; R 325.9075.
DCH Policy and Procedure 6.18 (Institutional Review Board)
DCH Policy and Procedure 11.1 (Newborn Screening Specimens)

G. CONTACT

For additional information concerning this policy, contact the Genomics and Genetic Disorders Section at 517-335-8887.

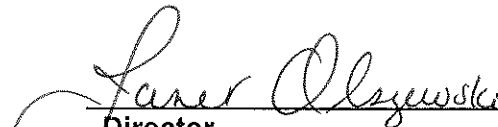
RECOMMENDED BY:


Deputy Director

DATE:

11/10/10

APPROVED BY:


Director

DATE:

11-11-10

Content Author: Corinne Miller, Bureau of Epidemiology